references fail to disclose each and every element of the claimed dispenser or method of calibrating. Appellants further suggest that even in combination with Poole et al., the cited references fail to establish the *prima facie* obviousness of the rejected claims.

The Examiner asserts that the modified device disclosed by Cox et al., Poole and Poole et al. has all of the structural limitations needed to perform the recited method steps, and is fully capable of doing so. Appellants respectfully disagree. As discussed above, even in combination, the cited references fail to disclose an inhaler having an accumulator, a sensor configured to sense medicament pressure within the accumulator, or a dispenser capable of regulating the pressure within the accumulator by opening and closing a valve in response to a sensed medicament pressure within the accumulator.

Claims 16-20

However, even if the combination of Cox et al., Poole, and Poole et al. were to generate a device capable of carrying out the method of claims 16-20, the Examiner is employing the wrong standard in determining the obviousness of the method claims. The fact that the references could be combined or modified does not establish *prima facie* obviousness unless the results would have been predictable to one of ordinary skill in the art. Appellants respectfully suggest that the references fail to provide sufficient guidance that a skilled artisan would be led to the method of claims 16-20, much less arrive at the claimed method with a reasonable expectation of its success.

For at least these reasons, Appellants respectfully suggest that claims 6, 7, and 16-20 are not rendered unpatentable by Cox et al., Poole, and Poole et al., and

Appellants request that the rejection of claims 6, 7, and 16-20 under 35 U.S.C. § 103 be withdrawn.

VII. (E) Conclusion

Appellants suggest that the references cited by the Examiner have failed to establish the *prima facie* obviousness of the rejected claims, and that the claimed invention is therefore not rendered unpatentable under 35 U.S.C. § 103(a).

Accordingly, the rejection of all pending claims should be reversed.

VIII. Claims Appendix

1. (Previously Presented) A medicament dispenser, comprising:

a medicament supply;

an ejector having a performance characteristic, the ejector being in fluid communication with the medicament supply;

an accumulator in fluid communication with the ejector;

a sensor configured to sense medicament pressure within the accumulator;

a valve intermediate the medicament supply and the accumulator, the valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector;

and

a controller configured to actuate the ejector using an operational parameter to produce a plurality of medicament drops having target drop characteristics, the operational parameter including a correction factor based on the performance characteristic of the ejector.

2. (Canceled)

3. (Canceled)

4. (Previously Presented) The medicament dispenser of claim 1, further comprising a compliant member that regulates pressure within the accumulator.

5. (Previously Presented) The medicament dispenser of claim 1, wherein the controller is configured to operate the valve to increase the medicament pressure within the accumulator.

6. (Original) The medicament dispenser of claim 1, wherein the performance characteristic of the ejector includes ejected drop volume.

7. (Original) The medicament dispenser of claim 1, wherein the performance characteristic of the ejector includes ejected drop weight.

8. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes drop ejection frequency.

9. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes number of drops ejected.

10. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes medicament pressure.

11. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes ejector temperature.

12. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes a static correction factor.

13. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes a dynamic correction factor.

14. (Previously Presented) An inhaler, comprising:

a medicament supply;

a medicament accumulator in fluid communication with the medicament supply;

a compliant member fluidically coupled to the medicament accumulator;

a valve intermediate the medicament supply and the medicament accumulator;

a sensor configured to sense a medicament pressure within the medicament accumulator;

an ejector in fluid communication with the medicament accumulator, wherein the ejector has a performance characteristic; and

a controller configured to apply a correction factor to an operational parameter of the ejector, wherein the correction factor is determined by the performance characteristic of the ejector.

15. (Previously Presented) A method of calibrating a medicament inhaler to a target output characteristic, the medicament inhaler having a medicament supply, a medicament accumulator in fluid communication with the medicament supply, a sensor configured to sense medicament pressure within the accumulator, a valve intermediate the medicament supply and the medicament accumulator, a medicament ejector in fluid communication with the medicament accumulator, and a controller configured to open and close the valve in response to a sensed medicament pressure within the accumulator, the method comprising:

manufacturing the medicament inhaler;

characterizing the output of the inhaler;

comparing the characterized output to the target output characteristic;

determining a correction factor to produce the target output from the inhaler; and

configuring the controller to apply the correction factor to the inhaler.

16. (Original) The method of claim 15, wherein characterizing the output of the inhaler includes determining an ejected drop weight.

17. (Original) The method of claim 16, wherein characterizing the output of the inhaler includes determining the ejected drop weight as a function of drop frequency.

18. (Original) The method of claim 16, wherein characterizing the output of the inhaler includes determining the ejected drop weight as a function of medicament ejector temperature.

19. (Original) The method of claim 15, wherein comparing the characterized output to the target output characteristic includes comparing a determined ejected drop weight to a target drop weight.

20. (Original) The method of claim 15, wherein determining a correction factor includes determining a corrected drop weight.

21. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a static correction factor.

22. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a dynamic correction factor.

23. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected drop ejection frequency.

24. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected number of drops ejected.

25. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected medicament fluid pressure.

26. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected ejector temperature.

27. (Previously Presented) The method of claim 26, wherein configuring the controller to apply the corrected ejector temperature includes configuring the controller to apply a corrected drop ejection frequency.

28. (Previously Presented) An inhaler, comprising:

a means for supplying fluid medicament;

a means for ejecting fluid medicament, the means having a performance characteristic;

a means for accumulating fluid medicament in fluid communication with the ejector means;

a means for sensing fluid medicament pressure within the accumulator means;

a means for regulating an addition of medicament to the accumulator means from the fluid medicament supply means in response to the pressure sensing means; and

a means for actuating the ejector means using an operational parameter calculated from the performance characteristic of the ejector means.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.

Respectfully submitted,

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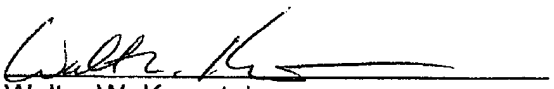

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Theresa Belland